

JSW

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re the Application of: **Garvey et al.**

Application No: **10/628,375**

Filed: **July 29, 2003**



Group Art Unit: **1626**

Examiner: **Kamal A. Saeed**

For: **Cyclooxygenase-2 Selective Inhibitors, Compositions and Methods of Uses**

Attorney Docket No: **102258.158 US2**

Commissioner of Patents  
PO Box 1450  
Alexandria, VA 22313-1450

**Provisional Response to Restriction Requirement and**  
**Request for Reconsideration of Restriction Requirement Under 37 C.F.R. § 1.143**

**I. Introductory Comments**

This response is submitted in reply to the Restriction Requirement dated October 6, 2005, for which a response is due on or before November 7, 2005 (the first business day after November 6, 2005).

No fee is believed to be due; however, the Commissioner is authorized to charge any necessary fees or credit any overpayments to Deposit Account No. 08-0219 to maintain the pendency of the present application.

**II. Request for Reconsideration of Restriction Requirement**

Under 37 C.F.R. §1.143, Applicants respectfully request reconsideration of the restriction requirement dated October 6, 2005.

The examiner restricted the invention as follows:

Group I	Claims 1, 2, 1-16 <sup>1</sup> , 28-39 and 55	Compounds and compositions in classes 544, 546, 548 and several subclasses
Group II	Claims 3-13, 17-27, 40-50	Methods of use for compounds of Formula I <sup>2</sup>

<sup>1</sup> Applicants assume that this is a typographical error and that the Examiner intended to refer to claims 14-16

<sup>2</sup> As confirmed by a telephone call to the Examiner from the undersigned on October 31, 2005, this is a typographical error and the Examiner intended to refer to compounds of Formula I to VIII.

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Group III	Claims 51-54 and 58	Kits classified in class 436
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The claims in the pending application are directed to compounds and compositions comprising **cyclooxygenase-2 inhibitor compounds**, kits comprising cyclooxygenase-2 inhibitor compounds, and the methods of use for the compounds and/or compositions.

**III. Restriction is Not Proper When the Claims are Related**

As stated in MPEP §808.02, “[w]here, as disclosed in the application, the several inventions claimed are related, and such related inventions are not patentably distinct as claimed, restriction under 35 U. S. C. §121 is never proper (MPEP §806.05).”

All the pending claims are related. Thus, the restriction requirement is not proper. To show that the inventions are distinct, the Examiner must show either that (1) there is a separate classification of the claims; (2) a separate status in the art when they are classifiable together; or (3) a different field of search. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

None of these three criteria have been shown with the claims of this application:

If the cyclooxygenase-2 inhibitor compounds and compositions of Formula (I) are allowable, then all the kits and methods of use for these compositions would also be allowable. In other words, every pending claim that requires a **cyclooxygenase-2 inhibitor compound** of Formula (I) would also be allowable. *In re Kase*, USPQ2d 1063 (US PTO Director, 2004).

A search of the prior art for the cyclooxygenase-2 inhibitor compounds and compositions of Formula (I) to (VIII) would necessarily encompass a search of the prior art for their methods of use and the kits comprising the compounds. Thus, the prior art for the cyclooxygenase-2 inhibitor compounds and compositions of the Examiner’s Group I respectively, will also be the same prior art for their methods of use and kits for the compositions comprising the cyclooxygenase-2 inhibitor compounds (i.e., Groups II and III).

**III. Proposed restriction requirement**

Applicants respectfully propose the following restriction requirement:

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Group I	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula I
Group II	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula II
Group III	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula III
Group IV	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula IV
Group V	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula V
Group VI	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VI
Group VII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VII
Group VIII	Claims 1-58 (in part)	Compounds, compositions, kits and methods of use for Formula VIII

**IV. Provisional Response to Restriction Requirement**

Applicants provisionally elect Group I, claims 1, 2, 14-16, 28-39 and 55-57 drawn to the compounds and compositions classified in classes 544, 546, 548 and several subclasses, with traverse.

**V. Election of Species**

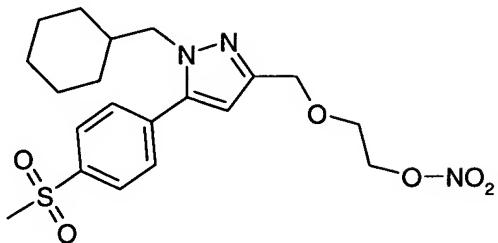
In response to the election of species requirement, Applicants elect the nitrosated cyclooxygenase inhibitor of Formula A, 4-(1-(cyclohexylmethyl)-3-((2-(nitrooxy)ethoxy)methyl)pyrazol-5-yl)-1-(methylsulfonyl)benzene, with traverse.

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This compound has the structure:



(A)

The synthesis of this compound is described in Example 2 of the specification at page 83, line 11 to page 85, line 19. The compound is encompassed by Formula II of the specification at, for example, page 40, line 16 to page 42, line 17.

**VI. Conclusion**

Applicants respectfully request that the restriction requirement be withdrawn and be replaced with Applicant's proposed restriction requirement.

An early and favorable consideration and allowance of the pending claims is respectfully requested.

Respectfully submitted,

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**Date: November 7, 2005**

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